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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/724,427

11/26/2003

Jim Mottola

37621/279.1

1046

69821

7590

06/03/2008

MERIT MEDICAL SYSTEMS, INC.

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EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

06/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/724,427	<b>Applicant(s)</b> MOTTOLA ET AL.	
	<b>Examiner</b> THEODORE J. STIGELL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-18, and 22-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Howell (3,949,745). Howell discloses a delivery system that could be used to intravenously deliver contrast media comprising a media reservoir (10), a spike (14a) for accessing the media in the reservoir, a length of tubing (16,24,26) linked to the spike, a primer bulb (38) connected in-line with the length of tubing, wherein the primer bulb is compressible to create a head of pressure above the media in the reservoir to facilitate the flow of the media into the length of tubing, a valve mechanism (42,44) that can provide a fluid tight seal to isolate the reservoir, length of tubing, and primer bulb from the inflow of air from the external environment, wherein the length of tubing and primer bulb are isolated from the external environment before compression of the primer bulb, wherein the valve is a one-way valve and comprises a venting door (44), wherein the valve mechanism is linked to the spike and the spike is a vented spike, and wherein the bulb is made of a polymeric material.

Claims 1-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Manzie (5,505,707). See Figure 2 and the respective portions of the specification. Manzie discloses a delivery system that could be used to intravenously deliver contrast media comprising a media reservoir (120), a spike (123) for accessing the media in the reservoir, a length of tubing (116,140) linked to the spike, a primer bulb (130) connected in-line with the length of tubing, wherein the primer bulb is compressible to create a head of pressure above the media in the reservoir to facilitate the flow of the media into the length of tubing, a valve mechanism (174) that can provide a fluid tight seal to isolate the reservoir, length of tubing, and primer bulb from the inflow of air from the external environment, wherein the length of tubing and primer bulb are isolated from the external environment before compression of the primer bulb, wherein the valve is a one-way valve and comprises a venting door, further comprising a stop-cock (150), wherein the valve mechanism is linked to the spike and the spike is a vented spike, and wherein the bulb is made of a polymeric material.

### ***Response to Arguments***

Applicant's arguments filed 3/7/2008 have been fully considered but they are not persuasive. In response to the applicant's argument that neither reference teaches a priming bulb adapted to "transmit air into a contrast media source to thereby create a head of pressure in the contrast media source" or that "increases the pressurization in the contrast media reservoir, such that the pressurization in the reservoir subsequent to actuation of the primer bulb is greater than the pressurization in the reservoir before actuation of the primer bulb", the examiner respectfully disagrees. The examiner

maintains that these limitations are functional and therefore the references only have to be capable of performing the functions. The examiner maintains that the priming bulbs in the references are structurally equivalent to the priming bulb in the instant application, and therefore the bulbs in the references could be adapted to perform the recited functions. The examiner suggests including more structural limitations.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone

Art Unit: 3763

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763